DEC 9 2 2006

K062517

August 9, 2006

510(k) SUMMARY

Electrosurgical Hemostatic Forceps Series

1 General Information

- Applicant:
  OLYMPUS MEDICAL SYSTEMS CORP.
  2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-850~
  Establishment Registration No: 8010047

- Official Correspondent:
  Laura Storms-Tyler
  Executive Director
  Regulatory Affairs & Quality Assurance
  Olympus America Inc.
  3500 Corporate Parkway
  PO Box 610
  Center Valley, PA 18034-0610, USA
  Phone: 484-896-5688
  FAX: 484-896-7128
  Email:Laura.storms-tyler@olympus.com
  Establishment Registration No: 2429304

- Manufacturer:
  Aomori Olympus
  248-1 Okkonoki 2-chome Kuroishi-shi,
  Aomori, Japan, 036-0367
  Establishment Registration Number: 9614641

2 Device Identification

- Device Trade Name: Electrosurgical Hemostatic Forceps Series
- Common Name: Electrosurgical Hemostatic Forceps
- Regulation Number: 21 CFR 876.4300/876.1500
- Regulation Name: Endoscopic electrosurgical unit and accessories
  Endoscope and accessories
- Regulatory Class: II
- Classification Panel: Gastroenterology and urology
  General and Plastic Surgery Devices
- Product Code: 78 KGE

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3 Predicate Device Information

Device Name	Common Name	510(k) No.	Manufacturer
FD-1L/U-1 Hot Biopsy Forceps	Hot Biopsy Forceps	K955052	Olympus Medical Systems Corp.
LSVP International Hot Biopsy Forceps	Hot Biopsy Forceps	K971204	LSVP International, Inc.

4 Device Description

The FD-1L/U-1 has been 510(k) cleared in K955052 for collecting tissue in the digestive tract. The subject FD-1L/U-1 has identical specification as the predicate cleared in K955052. This 510(k) submission is for the purpose of adding coagulation and hemostasis to the intended use. The FD-410LR is intended to be used for coagulation and hemostasis only. Although its cup shape is different from that of the FD-1L/U-1, coagulation and hemostasis abilities are the same.

5 Indications for Use

FD-1L/U-1 Hot Biopsy Forceps

This instrument has been designed to be used with Olympus endoscopes to collect tissue, cauterize, coagulate and perform hemostasis using high-frequency current within the digestive tract.

FD-410LR Single Use Electrosurgical Hemostatic Forceps

This instrument has been designed to be used with Olympus endoscopes to cauterize, coagulate and perform hemostasis using high-frequency current within the digestive tract.

6 Comparison of Technological Characteristics

The FD-1L/U-1 and FD-410LR are basically identical to the predicate device in intended use, and similar in specifications except for addition of coagulation and hemostasis indications.

7 Conclusion

When compared to the predicate device, the FD-1L/U-1 and FD-410LR do not incorporate any significant changes that could affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Ms. Laura Storms-Tyler
Executive Director
Regulatory Affairs & Quality Assurance
Olumpus America Inc.
3500 Corporate Parkway
P.O. Box 610
CENTER VALLEY PA 18034-0610

DEC 22 2006

Re: K062517
Trade/Device Name: Electrosurgical Hemostatic Forceps Series
Regulation Number: 21 CFR §876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: KGE
Dated: November 28, 2006
Received: December 1, 2006

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062517

Device Name: Electrosurgical Hemostatic Forceps Series

Indications For Use:

FD-1L/U-1 Hot Biopsy Forceps

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FD-410LR Single Use Electrosurgical Hemostatic Forceps

This instrument has been designed to be used with Olympus endoscopes to cauterize, coagulate and perform hemostasis using high-frequency current within the digestive tract.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062517